

**IN THE UNITED STATES PATENT AND TRADEMARK
OFFICE**

In re:	Application No. 10/511,888)	<i>Confirmation No. 4210</i>
Filed:	October 19, 2004)	
Applicants:	Dirk Cremer et al.)	
Title:	MATRIX COMPRISING A BIOACTIVE COMPONENT CONTAINING PHOSPHOLIPID)	
Art Unit:	1618)	
Examiner:	Blessing M. Fubara)	
Attorney Docket:	5942/83518)	
Customer No.:	22242)	
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)	
			This Declaration was electronically filed on <u>July 20, 2009</u> using the USPTO's EFS-Web.

DECLARATION OF ELISABETH MARKL

I, Elisabeth Markl, declare as follows:

1. I am the inventor of the above entitled patent application.
2. My education includes an apprenticeship as a chemical laboratory assistant.
3. I have been involved in the development in pharmaceutical compositions which effect health benefits. In my employment I did the following work in developing pharmaceutical/nutraceutical compositions: Set up analytical methods and conduct stability testing of galenic formulations with

particular focus on measuring the active ingredient based on the SOPs provided by the head of the laboratory. My involvement in this work was from August 01, 2001 to December 2003.

4. The compositions described in the instant above identified patent application include a matrix with a bioactive component which includes phosphatidyl serine and phosphatidyl choline. As described in the specification of the instant application identified above, because these materials act as emulsifiers, the encapsulation of phospholipids often causes problems such as the capsules becoming permeable in short times. This causes the capsules to leak. The matrix described in the instant application is extremely stable, is solid or very viscous, and additionally has thixotropic properties as shear thinning or dilution.

5. I have read WO 01/84961 (Kiliaan). Kiliaan, such as in Example 1, describes a capsule which includes as active components phosphatidyl serine, phosphatidyl choline, omega fatty acids, and vitamins. The latter blend, however, does not have these ingredients in an amount and ratio that would make any whole matrix solid or paste-like at room temperature or make the blend highly viscous and have shear dilution properties to provide the stability described in the matrix of the instant above application.

6. Kiliaan et al. do not describe a stable solid matrix. Because the amounts and relative amounts of phosphatidyl serine and fatty acids are lower than what is described in the above instant application, based upon my experience, the capsule described in Kiliaan's Example 1 would not be a dosage form which

becomes a solid matrix at room temperature, nor would it have the shear dilution properties as described in the above instant application.

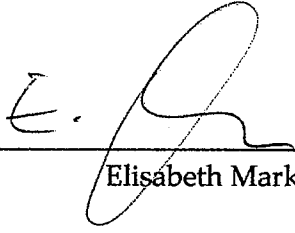
7. Further, by virtue of my experience in formulating materials with phospholipids, due to the amounts of fatty acids in Kiliaan's Example 1, a stable matrix would not be formed. As a result, Kiliaan's blend of ingredients and relative amounts of ingredients would not provide the properties and stability described and sought in the instant above identified application. Also, Kiliaan's composition of Example 1 contains a mixture of herbal extracts which would not promote stability of any matrix in Killiaan's blend.

8. It also is my understanding there has been a question raised about how a person of ordinary skill in the technology described in the instant application would understand the phrases "derivatives of tocopherols" and "derivatives of tocotrienols." Vitamin E is a collective name for eight compounds: the chemical compounds α -tocopherol, β -tocopherol, γ -tocopherol and δ -tocopherol and α -tocotrienol, β -tocotrienol, γ -tocotrienol and δ -tocotrienol. As can also be seen from a German article, derivatives of these compounds also are well known. That German article states "Tocopherol acetate, tocopherol succinate, tocopherol nicotinate and tocopherolpoly-(oxyethylene) succinate (International non-proprietaryname:Tocofersolate) are the usual dosage forms for the application of vitamin E. Hence, in my experience in the technology of the instant application, a person of ordinary skill would understand the phrases "derivatives of tocopherols" and "derivatives of tocotrienols."

The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize

the validity of the application or any patent issuing thereon, hereby declares that the above statements made of my own knowledge are true and that all statements made on information and belief are believed to be true.

Date: 2009-06-18



Elisabeth Markl